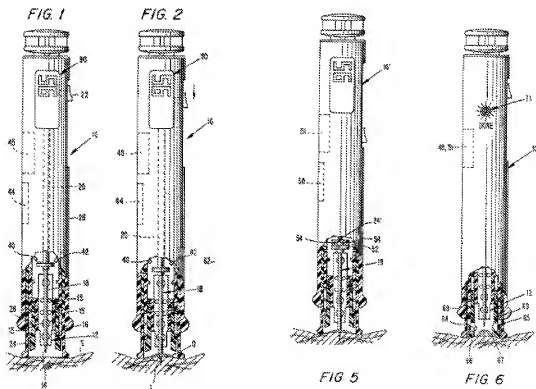


## II. REMARKS

A non-final Office Action was issued in this application on November 24, 2009 (hereinafter "Non-final Office Action"). This submission is believed to be fully responsive to the Non-final Office Action. Claims 1-7 and 10-35 are pending in this application; all pending claims presently stand rejected. There are no amendments to the claims, specification or drawings presented herein. As such, claims 1-7 and 10-35 remain pending. Reconsideration and allowance of this application in view of the following remarks is respectfully requested.

### A. CLAIM REJECTIONS - 35 U.S.C. 103

Claims 1-7 and 10-35 are rejected under 35 U.S.C. § 103(a) over U.S. Patent No. 5,951,492, to Douglas et al. (hereinafter "Douglas"), in view of U.S. Patent Application Publ. No. 2003/0171696 A1, to Dosmann (hereinafter "Dosmann"), and U.S. Patent Application Publ. No. 2004/0127818 A1, to Roe et al. ("Roe"). Applicants respectfully traverse this rejection.



The Examiner states that Douglas discloses a lancing apparatus 10 for collecting a body fluid sample, comprising a body 26, a disposable lancet 12 with a needle 14, and a capillary tube 18 for collecting the body fluid, as seen in FIG. 1 (recreated above). *See* First Office Action, Item No. 2, at 2. Douglas is also said to show a lancing mechanism for moving the lancet 12

between a retracted position (FIG. 1) and a lancing position (FIG. 2, recreated above), and for moving the capillary tube 18 to the lancing site for collecting body fluid. *See id.* The Examiner also states that Douglas discloses an outer end cap 24 with an aperture, and an inner end cap (shown in FIGS. 1 and 2, but labeled only in FIG. 6 at 66) coupled to the body 10 and disposed within the outer end cap 24. *See id.*, at 2-3.

The Examiner acknowledges, however, that Douglas does not disclose (1) a hollow lancet where the interior of the lancet forms a channel for moving the fluid sample from the tip to a reaction area; (2) a lancing mechanism providing a collecting position; and (3) the outer end cap and the inner end cap remaining in contact with the skin when in the lancing position to assist in sample formation and collection. *See First Office Action*, Item No. 2, at 3. The Examiner therefore applies Dosmann for teaching an optical format 10 (FIG. 1) with a hollow lance 12, the interior of which forms a channel 13 for moving a fluid sample from the sharp tip 16 to a reaction area. *See id.*, at 3-4. The Examiner also applies Roe for allegedly teaching an inner end cap 82 disposed within an outer end cap 46 (FIG. 2), where the outer and inner end caps 46, 82 remain in contact with the skin when in the lancing position to assist in sample formation and collection. *See id.*, at 4. The Examiner concludes that it would have been obvious to substitute Douglas' disposable lancet (i.e., needle 12, capillary tube 18, and test element 30) with Dosmann's hollow lancet 10, and to modify Douglas' end caps 24, 66 to both remain in contact with the skin during the lancing position as taught by Roe. Applicants respectfully traverse this rejection as contrary to MPEP guidelines and violative of Federal Judicial mandates.

A proper rejection under § 103(a) requires the examiner establish *prima facie* obviousness. The legal concept of *prima facie* obviousness is a procedural tool of examination, allocating who has the burden of going forward with production of evidence in each step of the examination process. *See* MPEP 2142. Of notable importance, it is “[t]he examiner [who] bears the initial burden of factually supporting any *prima facie* conclusion of obviousness.” MPEP § 2142 (emphasis in original). *See, also*, MPEP 2106 (“The burden is on the USPTO to set forth a *prima facie* case of unpatentability.” Emphasis in original.) In fact, if the examiner fails to make a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness. *See* MPEP § 2142.

To properly substantiate a *prima facie* case of obviousness under § 103(a), the applied references must teach, suggest, or otherwise disclose each and every element and limitation of

the rejected claim(s). See *In re Kotzab*, 217 F.3d 1365, 1369-71 (Fed. Cir. 2000); *In re Royka*, 490 F.2d 981 (CCPA 1974). In setting forth a *prima facie* case, the examiner may not opportunistically disregard certain claim terms; rather, “[e]very word[] in a claim must be considered in judging the patentability of a claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 1385 (CCPA 1970). In effect, “[w]hen determining whether a claim is obvious, an examiner must make ‘a searching comparison of the claimed invention - including all its limitations - with the teaching of the prior art.’” *In re Ochial*, 71 F.3d 1565, 1572 (Fed. Cir. 1995).

In addition to demonstrating that the applied art teaches every element and limitation of a rejected claim, the law of obviousness requires the reviewing examiner to clearly articulate “an apparent reason” why a person skilled in the art would be compelled to combine “the known elements” to achieve the invention “claimed by the patent at issue”. *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007). “[R]jections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006). To that extent, the mere fact that references can be combined or modified does not render the resultant combination obvious. See MPEP 2143.01 (III). The Supreme Court has clarified that a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. *KSR Int’l*, 127 S. Ct. at 1741. Rather, there must be “an apparent reason to combine the known elements in the fashion claimed by the patent at issue,” and such reasoning must “be made explicit.” *Id.*, at 1742.

Section 2143.01(VI) of the MPEP notes that an examiner’s proposed modification of a cited reference is not sufficient to render a claim *prima facie* obvious “[i]f the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified”. Citing *In re Ratti*, 270 F.2d 810 (CCPA 1959). The court in *Ratti* emphasized that a proposed modification which “change[s] the basic principle under which the [primary reference’s] construction was designed to operate” is grounds for overturning a finding of obviousness. See, also, MPEP 2143.01(VI) and 2145(III).

A claimed invention cannot be statutorily “obvious” where the prior art teaches away from the claimed invention. See e.g., *In re Peterson*, 315 F.3d 1325, 1331 (Fed. Cir. 2003); *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1354 (Fed. Cir. 2001). It is therefore axiomatic that each reference be considered in its entirety, especially portions that teach away from an applicant’s

claimed invention. *See* MPEP § 2141.02. A prior art reference may be considered to “teach away” when “a person of ordinary skill, upon reading the reference ... would be led in a direction divergent from the path that was taken by the applicant.” *Tec Air, Inc. v. Denso Mfg. Mich. Inc.*, 192 F.3d 1353, 1360 (Fed. Cir. 1999). Of paramount significance, the Federal Circuit has unequivocally held “that references that teach away cannot serve to create a *prima facie* case of obviousness.” *In re Gurley* 27 F.3d 551, 553 (Fed. Cir. 1994), citing *In re Spinnoble*, 405 F.2d 578, 587 (CCPA 1969).

The pending § 103(a) rejection is improper for at least four reasons: first, there is no teaching or suggestion to combine Douglas and Dosmann; second, Douglas explicitly teaches away from the Examiner’s proposed modifications; third, the Examiner’s proposed modifications would change the principle of operation of the Douglas reference.

***1. There is no teaching or suggestion to combine Douglas with Dosmann.***

There is no teaching or suggestion to combine Douglas and Dosmann. The Examiner proposes that if would have been obvious to substitute Douglas’ disposable lancet 12, needle 14, capillary tube 18, and test element 30 with Dosmann’s hollow lancet 10 for lancing the skin and collecting fluid to improve test time by integrating the lance, harvest and analysis operation as taught by Dosmann. *See* First Office Action, at 4. Contrary to this allegation, a person of ordinary skill in the art would not be motivated to modify Douglas to include Dosmann’s hollow lancet 10. The lance 10 taught by Dosmann is unmovable and, thus, has a single position. The housing 18 of Dosmann controls the depth of a puncture into a patient’s skin by the lance 12 – i.e., the depth of a puncture corresponds to the length of the lance 12 extending out of the housing 18. Douglas’ disposable lancet 12, on the other hand, is adapted to move between retracted and lancing positions. As such, a person of ordinary skill in the art would not have an apparent reason or motivation to substitute Douglas’ movable lancet 12 with Dosmann’s stationary lancet 10, as proposed in the First Office Action.

Additionally, Dosmann discloses a disposable optical format/integrated lance 10 for lancing the skin, whereas Douglas only discloses a reusable lancing device 10. That is, the lancing device disclosed in Douglas is reusable after the disposable lancet 12, capillary tube 18 and test strip 30 are discarded. Thus, the devices disclosed in Dosmann and Douglas have different uses –

the lance of Dosmann is disposable, while the lancing device of Douglas is reusable. Accordingly, there would be no apparent reason or motivation to incorporate Dosmann's disposable lancet 10 into Douglas' reusable lancing device 10, as proposed by the Examiner.

*2. Douglas explicitly teaches away from the proposed modifications.*

Douglas teaches away from modifying the end caps 24, 66, as proposed by the Examiner, to both remain in contact with the skin during lancing as taught by Roe. Douglas teaches that the drop sensing mechanism 65 (FIG. 6), which is mounted on the inside perimeter of the inner sleeve 66, is used to determine whether a drop of body fluid expressed from an incision is of sufficient size to provide a proper sample. *See* Douglas, Col. 7, Ln. 29-35. The drop sensing mechanism comprises a pair of diametrically opposed electrodes 67, 68 that are connected by wires 69 to a battery 45 or 51. *See id.*, Ln. 35-36. The electrodes 67, 68 are "positioned such that when the outer sleeve 24 is retracted in response to a pressing down of the housing," the electrodes will contact the drop of body fluid only if the drop is of sufficient height to provide an adequate sample. *See id.*, Ln. 36-42. If such contact is made, the drop will close a circuit, enabling a sensor to determine that the drop is of ample size. In other words, Douglas explicitly states that the inner sleeve 66 is in contact with the skin only when the lancing is complete and the outer sleeve 24 is retracted. As such, a person of ordinary skill in the art, upon reading Douglas, would be led in a direction divergent from the path taken by Applicants. Accordingly, the Examiner's proposed modification of Douglas in light of Roe is improper and conflicts with MPEP directives and Federal Judicial standards.

*3. The proposed modifications would change the principle of operation of the Douglas reference.*

A person of ordinary skill in the art would not be motivated to modify Douglas' end caps 24, 66 to both remain in contact with the skin during the lancing position as taught by Roe because this would change the principle of operation of the Douglas reference. Douglas teaches that the stimulator sleeve 24 (designated by the Examiner as the "outer end cap") depresses a ring of body tissue in surrounding relationship to the incision, causing the incision to bulge while spreading apart the sides of the incision, as seen in FIG. 1. *See* Douglas, Col. 5, Ln. 51-54. The

purported advantage to this design is that a drop of body fluid is formed at the open end of the incision even if the incision is made in a region of the body where the supply of body fluid is relatively low as compared to, say, the fingertip region. *See id.*, Ln. 54-58. Modifying Douglas such that the end caps 24, 66 both remain in contact with the skin during the lancing position, as proposed by the Examiner, would eliminate this feature - i.e., the inner sleeve 66 would press down on the patient's skin and eliminate the bulge of body tissue. Accordingly, the Examiner's proposed modification is improper because it is in direct conflict with the teachings of Douglas, and would change the principle of operation of Douglas' lancing apparatus 10.

A person of ordinary skill in the art would not be motivated to substitute Douglas' disposable lancet with Dosmann's hollow lancet because this would change the principle of operation of the Douglas reference. Douglas unequivocally states that one object of his invention "is to enable a sample of body fluid to be applied to a test strip which is mounted in a lancing device." Douglas, Col. 3, Ln. 24-25. Another object of Douglas' invention is "to provide a device for minimally invasive sampling comprising a reusable sampler and disposable lancet and sample collection device." Douglas achieves these touted objectives with the disposable lancet 12 having an integral capillary tube 18 with a test strip 30 bonded thereto. *See id.*, FIGS. 1-4; Col. 3, Ln. 64, -Col.4, Ln. 10; Col. 4, Ln. 18-25; Col. 5, Ln. 25-67. This averment is further buttressed by Douglas' claims, all of which require inclusion of the disposable lancet. Eliminating this feature, as proposed by the Examiner, would change one of the basic principles under which Douglas' lancing device was designed to operate; as such, the Examiner's proposed modification is not sufficient to render Applicants' claims *prima facie* obvious. *See* MPEP 2143.01(VI) and 2145(III); *In re Ratti*, 270 F.2d at 813.

For at least the foregoing reasons, the pending § 103(a) rejection of claims 1-7 and 10-35 is erroneous and should therefore be withdrawn.

### III. CONCLUSION

In light of the reasoning and remarks set forth above, this submission is believed to be fully responsive to the Office Action dated November 24, 2009. The remarks in support of the rejected claims are believed to place this application in condition for allowance, which action is herein respectfully requested. If the Examiner believes that a personal conference with Applicants' attorney will help expedite prosecution of the captioned application, the Examiner is reverently invited to contact the undersigned at his soonest convenience via the correspondence information presented below.

\* \* \* \* \*

The Commissioner is hereby authorized to charge any necessary fees associated with this amendment (except for payment of the issue fee) to Nixon Peabody, LLP, Deposit Account No. 50-4181, Order No. 247082-000090USPX.

Respectfully submitted,

Date: February 19, 2010

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